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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,563	05/09/2008	Jiunn-Liang Ko	8964-000031/US	5069

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HARNESS, DICKEY & PIERCE, P.L.C.  
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EXAMINER
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NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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06/28/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,563	<b>Applicant(s)</b> KO ET AL.	
	<b>Examiner</b> Mark Navarro	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,11,12,17-21 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5-8,11,12,17-21 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants amendment filed June 8, 2010 has been received and entered. Claims 1-2, 5-8, 11-12, 17-21, and 24-30 are pending in the instant application, of which claims 1-2, 5-8, 11-12, 17-21 and 24-28 have been withdrawn from further consideration as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of claims 29-30 under 35 U.S.C. 102(b) as being anticipated by Little et al is maintained.

Applicants are asserting that in Little the BPI protein has antifungal activity, which acts as an antibiotic, while the main function for the fungal immunomodulatory protein (FIP) of the instantly filed claims is facilitating and improving the immune system. Applicants further assert that Little et al does not teach or suggest orally administering FIP to a subject as recited in claim 29.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that in Little the BPI protein has antifungal activity, which acts as an antibiotic, while the main function for the fungal immunomodulatory protein (FIP) of the instantly filed claims is facilitating and improving the immune system. However, Applicants will hopefully appreciate that claim 29 does not recite any function of “improving the immune system” and consequently cannot be used to distinguish over the prior art. The sole active step recited in claim 29 is “administering a fungal immunomodulatory protein.” This is precisely what Little et al did, even if the antifungal activity was acting as an antibiotic, it meets the requirements of claim 29 which recites a protein having “fungal immunomodulatory” properties. While the BPI protein disclosed by Little et al may have structural differences with the FIP protein of the instant invention, Applicants claim 29 does not point out any of these structural differences (e.g., wherein the fungal immunomodulatory protein comprises the amino acid sequence of SEQ ID NO: X). Amendment of the claims to recite such a structural difference may be sufficient to overcome this rejection. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Finally, Applicants assert that Little et al does not teach or suggest orally administering FIP to a subject as recited in claim 29. However, Applicants are again respectfully directed to claim 14 of Little et al which discloses methods of treating fungal infections comprising orally administering the peptide having antifungal activity.

The claims are directed to a method of modulating immunological activities comprising orally administering fungal immunomodulatory protein or protein fused with FIP to a subject.

Little et al (US Patent Number 5,858,974) disclose of peptides of human bactericidal/permeability-increasing protein (BPI) from about position 148 to about position 161 of SEQ ID NO: 251 which have antifungal activity. (See claim 1). Little et al further disclose of treating fungal infections by administering the peptide orally to a subject. (See claim 14). Little et al further disclose that the peptide can be synthesized or recombinantly produced. (See detailed paragraph 13).

Accordingly, the disclosure of Little et al is deemed to anticipate each and every limitation of the instant claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/  
Primary Examiner, Art Unit 1645  
June 22, 2010